

**No. 24-1098**

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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**BRITA LP,**

*Appellant,*

v.

**INTERNATIONAL TRADE COMMISSION,**

*Appellee,*

**ZERO TECHNOLOGIES, LLC; CULLIGAN INTERNATIONAL CO.;  
VESTERGAARD FRANDSEN INC., D/B/A LIFESTRAW; KAZ USA, INC.;  
HELEN OF TROY LIMITED,**

*Intervenors.*

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On Appeal from the United States International Trade Commission,  
Investigation No. 337-TA-1294

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**RESPONSE BRIEF OF APPELLEE  
INTERNATIONAL TRADE COMMISSION**

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## PATENT CLAIM

### Claim 1 of U.S. Patent No. 8,167,141 (Appx423)

1. A gravity-fed water filter, comprising:

filter media including at least activated carbon and a lead scavenger;  
wherein the filter achieves a Filter Rate and Performance (FRAP)  
factor of about 350 or less according to the following formula:

$$FRAP = \frac{[V * f * c_e]}{[L * 2]}$$

where:

V = volume of the filter media (cm<sup>3</sup>),

f = average filtration unit time over lifetime L (min/liter),

c<sub>e</sub> = effluent lead concentration at end of lifetime L when source water  
having a pH of 8.5 contains 90-120 ppb (µg/liter) soluble lead and 30-60 ppb  
(µg/liter) colloidal lead greater than 0.1 µm in diameter, and

L = filter usage lifetime claimed by a manufacturer or seller of the filter  
(gallons).

## TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES .....	iii
STATEMENT OF RELATED CASES .....	1
STATEMENT OF THE ISSUES.....	1
STATEMENT OF THE CASE.....	2
I. THE ASSERTED PATENT .....	2
II. THE COMMISSION PROCEEDINGS .....	8
A. Lack of Written Description.....	8
B. Lack of Enablement.....	12
C. Indefiniteness.....	17
SUMMARY OF THE ARGUMENT .....	21
ARGUMENT .....	23
I. STANDARD OF REVIEW.....	23
II. SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION’S DETERMINATION THAT THE ASSERTED CLAIMS ARE INVALID FOR LACK OF WRITTEN DESCRIPTION.....	25
A. The Art Is Unpredictable with Respect to the Claimed FRAP .....	26
B. The Specification Fails to Support the Full Breadth of the Claims.....	32
C. The Disclosed Carbon-Block Filter Embodiments Are “Unique” and Are Not Representative of All Media Filters .....	38
III. SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION’S DETERMINATION THAT THE ASSERTED CLAIMS LACK ENABLEMENT .....	40
A. Under the <i>Wands</i> Factors, the Full Scope of the Asserted Claims Lacks Enablement.....	41
B. Contrary to Brita’s Assertion, this Court’s Precedent Supports the Commission’s Lack of Enablement Determination .....	49

IV.	THE COMMISSION CORRECTLY DETERMINED THAT THE TERM “FILTER USAGE LIFETIME CLAIMED BY A MANUFACTURER OR SELLER OF THE FILTER” CANNOT BE ASCERTAINED WITH REASONABLE CERTAINTY, THEREBY RENDERING THE CLAIMS INDEFINITE .....	51
A.	The Claims Demonstrate a Subjective “Lifetime” Limitation, and There Is No Support for Rewriting the Claim Language to Include an Objective “Validation” Term .....	52
B.	The Patent Fails to Provide an Objective Methodology that Would Circumscribe the Disputed Limitation .....	56
C.	This Court’s Precedent Supports the Commission’s Indefiniteness Determination .....	60
	CONCLUSION .....	62

## TABLE OF AUTHORITIES

<b><u>Cases</u></b>	<b><u>Page(s)</u></b>
<i>Ajinomoto Co. v. ITC</i> , 932 F.3d 1342 (Fed. Cir. 2019) .....	39
<i>Alcon Rsch. Ltd., v. Barr Labs.</i> , 745 F.3d 1180 (Fed. Cir. 2014) .....	50, 51
<i>ALZA Corp. v. Andrx Pharms., LLC</i> , 603 F.3d 935 (Fed. Cir. 2010) .....	40, 41, 50
<i>Amgen Inc. v. Sanofi</i> , 598 U.S. 594 (2023).....	40, 44, 50, 51
<i>Amgen Inc. v. Sanofi, Aventisub LLC</i> , 987 F.3d 1080 (Fed. Cir. 2021) .....	25, 49
<i>Ariad Pharm., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) ( <i>en banc</i> ) .....	<i>passim</i>
<i>BASF Corp. v. Johnson Matthey Inc.</i> , 875 F.3d 1360 (Fed. Cir. 2017) .....	53
<i>Baxalta Inc. v. Genentech, Inc.</i> , 81 F.4th 1362 (Fed. Cir. 2023) .....	41
<i>Bio-Rad Labs., Inc. v. ITC</i> , 998 F.3d 1320 (Fed. Cir. 2021) .....	23
<i>Biosig Instruments, Inc. v. Nautilus, Inc.</i> , 783 F.3d 1374 (Fed. Cir. 2015) .....	61
<i>CAE Screenplates Inc. v. Heinrich Fiedler GmbH</i> , 224 F.3d 1308 (Fed. Cir. 2000) .....	54
<i>Cephalon, Inc. v. Watson Pharms., Inc.</i> , 707 F.3d 1330 (Fed. Cir. 2013) .....	50
<i>Chef Am., Inc. v. Lamb Weston, Inc.</i> , 358 F.3d 1371 (Fed. Cir. 2004) .....	54

**TABLE OF AUTHORITIES (cont'd)**

<b><u>Cases (cont'd)</u></b>	<b><u>Page(s)</u></b>
<i>Datamize, LLC v. Plumtree Software, Inc.</i> , 417 F. 3d 1342 (Fed. Cir. 2005) .....	53, 60
<i>Deere &amp; Co. v. ITC</i> , 605 F.3d 1350 (Fed. Cir. 2010) .....	22
<i>Dow Chem. Co. v. Nova Chems. Corp. (Canada)</i> , 803 F.3d 620 (Fed. Cir. 2015) .....	58
<i>Falko-Gunter Falkner v. Inglis</i> , 448 F.3d 1357 (Fed. Cir. 2006) .....	37
<i>Finnigan Corp. v. ITC</i> , 180 F.3d 1354 (Fed. Cir. 1999) .....	59
<i>Guangdong Alison Hi-Tech Co. v. ITC</i> , 936 F.3d 1353 (Fed. Cir. 2019) .....	21
<i>Hill-Rom Servs., Inc. v. Stryker Corp.</i> , 755 F.3d 1367 (Fed. Cir. 2014) .....	59
<i>i4i Ltd. P'ship v. Microsoft Corp.</i> , 598 F.3d 831 (Fed. Cir. 2010) .....	56
<i>ICU Med., Inc. v. Alaris Med. Sys., Inc.</i> , 558 F.3d 1368 (Fed. Cir. 2009) .....	36, 37
<i>Interactive Gift Express, Inc. v. Compuserve Inc.</i> , 256 F.3d 1323 (Fed. Cir. 2001) .....	52
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014) .....	56, 60
<i>Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.</i> , 97 F.4th 915 (Fed. Cir. 2024) .....	24
<i>Juno Therapeutics, Inc. v. Kite Pharma, Inc.</i> , 10 F.4th 1330 (Fed. Cir. 2021) .....	37, 38

**TABLE OF AUTHORITIES (cont'd)**

<b><u>Cases (cont'd)</u></b>	<b><u>Page(s)</u></b>
<i>Kay v. FCC</i> , 396 F.3d 1184 (D.C. Cir. 2005).....	22
<i>Liebel–Flarsheim Co. v. Medrad, Inc.</i> , 481 F.3d 1371 (Fed. Cir. 2007) .....	50
<i>LizardTech, Inc. v. Earth Res. Mapping, Inc.</i> , 424 F.3d 1336 (Fed. Cir. 2005) .....	36
<i>McRO, Inc. v. Bandai Namco Games Am. Inc.</i> , 959 F.3d 1091 (Fed. Cir. 2020) .....	46
<i>Microsoft Corp. v. i4i Ltd. P’ship</i> , 564 U.S. 91 (2011).....	24
<i>Morall v. DEA</i> , 412 F.3d 165 (D.C. Cir 2005).....	42
<i>Morton Int’l, Inc. v. Cardinal Chem. Co.</i> , 5 F.3d 1464 (Fed. Cir. 1993) .....	56
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 572 U.S. 898 (2014).....	24, 51
<i>Novartis Pharms. Corp. v. Accord Healthcare, Inc.</i> , 38 F.4th 1013 (Fed. Cir. 2022) .....	24
<i>Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy’s Labs. Inc.</i> , 923 F.3d 1368 (Fed. Cir. 2019) .....	25
<i>ScriptPro LLC v. Innovation Assocs., Inc.</i> , 833 F.3d 1336 (Fed. Cir. 2016) .....	35, 36
<i>Sinorgchem Co., Shandong v. ITC</i> , 511 F.3d 1132 (Fed. Cir. 2007) .....	21
<i>Sitrick v. Dreamworks, LLC</i> , 516 F.3d 993 (Fed. Cir. 2008) .....	50

## TABLE OF AUTHORITIES (cont'd)

<b><u>Cases (cont'd)</u></b>	<b><u>Page(s)</u></b>
<i>Solomon Techs., Inc. v. ITC</i> , 524 F.3d 1310 (Fed. Cir. 2008) .....	21
<i>Spansion Inc. v. ITC</i> , 629 F.3d 1331 (Fed. Cir. 2010) .....	22, 42
<i>Teva Pharms. USA, Inc. v. Sandoz Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015) .....	58
<i>Teva Pharms. USA, Inc. v. Sandoz, Inc.</i> , 574 U.S. 318 (2015).....	24
<i>The Incandescent Lamp Patent</i> , 159 U.S. 465 (1895) .....	40, 44, 50
<i>Univ. of Rochester v. G.D. Searle &amp; Co.</i> , 358 F.3d 916 (Fed. Cir. 2004) .....	40
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996) .....	59
<i>In re Wands</i> , 858 F.2d 731 (Fed. Cir. 1988) .....	<i>passim</i>
<i>Wellman, Inc. v. Eastman Chem. Co.</i> , 642 F.3d 1355 (Fed. Cir. 2011) .....	61
<b><u>Statutes</u></b>	
5 U.S.C. § 557(b) .....	22
5 U.S.C. § 706.....	23
19 U.S.C. § 1337.....	<i>passim</i>
35 U.S.C. § 112.....	36, 52
35 U.S.C. § 282.....	24



**TABLE OF AUTHORITIES (cont'd)**

<b><u>Regulations</u></b>	<b><u>Page(s)</u></b>
19 C.F.R. § 210.43(b) .....	59
19 C.F.R. § 210.43(c).....	59

## **STATEMENT OF RELATED CASES**

Other than the cases identified by Appellant Brita LP (“Brita”), Appellee International Trade Commission (“Commission”) is unaware of any other cases pending in this or any other court or agency that will directly affect or be directly affected by this Court’s decision in the pending appeal.

## **STATEMENT OF THE ISSUES**

The issues in the present appeal are properly framed as follows:

1. Whether substantial evidence supports the Commission’s determination that the Intervenor<sup>1</sup> demonstrated clearly and convincingly that the asserted claims of U.S. Patent No. 8,167,141 (“the ’141 patent”) are invalid for lack of adequate written description support.
2. Whether the Commission correctly determined that the Intervenor demonstrated clearly and convincingly that the asserted claims are invalid because the patent disclosure fails to enable the full scope of the claimed invention.
3. Whether the Commission correctly determined that the scope of the claim term “filter usage lifetime claimed by a manufacturer or seller of the filter” cannot be ascertained with reasonable certainty, thereby rendering the asserted patent claims indefinite.

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<sup>1</sup> “Intervenor<sup>1</sup>” are Zero Technologies, LLC; Culligan International Co.; Vestergaard Frandsen Inc., d/b/a LifeStraw; Kaz USA, Inc.; and Helen of Troy Limited.

## STATEMENT OF THE CASE

The Commission provides this Statement of the Case for a more complete description of the relevant facts and findings.

The Commission instituted the underlying investigation on January 31, 2022, as Investigation No. 337-TA-1294, *Certain High-Performance Gravity-Fed Water Filters and Products Containing the Same*, based on a complaint filed by Brita against Intervenors and other respondents (collectively, “Respondents”), the latter of which were subsequently terminated from the investigation. Appx3-4. The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), based on the importation into the United States of gravity-fed water filters accused of infringing the ’141 patent. Appx648. On appeal, Brita challenges the Commission’s final determination of no violation of section 337 which was based on the Commission’s findings of invalidity of the asserted patent claims for lack of written description, lack of enablement, and indefiniteness.

### I. THE ASSERTED PATENT

The ’141 patent relates generally to gravity-flow water filtration systems used for removing undesirable contaminants in drinking water, such as lead. Appx407. The patent states that “[t]he present invention relates to gravity flow filtration systems, and more particularly, this invention relates to carbon block and

granular filters having rapid flow rates and excellent filtration performance.”

Appx407 (1:15-18). The claimed invention pertains to home water treatment systems to treat tap water. Appx407 (1:22-23). Two basic types of water treatment systems for household use are known in the art: (1) a pressurized system, such as a filter mounted to a faucet; and (2) a low-pressure system that operates under the force of gravity as water flows through a filter into a water collection receptacle as shown in the example below:



Appx407 (1:33-39); Appx93. The '141 patent relates to the second type.

The patent explains that “[f]iltration of water in a pressurized system has the advantage of the pressure to drive the filtration through the carbon block and therefore does not usually face problems of achieving desired flow rate while maintaining effective filtration of contaminants.” Appx407 (1:40-44). The patent notes, however, that “when carbon blocks designed for pressurized systems are

applied to gravity-fed systems, they fail to produce the desired flow rates consistently over time” and that “[f]iltration of water in a low-pressure system faces the challenge of undesirable contaminants while maintaining a desired high flow rate.” Appx407 (1:44-49). The patent acknowledges that “[f]ilter blocks for water filtration comprising granular activated carbon” that utilize “hollow, cylindrical activated carbon blocks” have been commercially available for many years.” Appx407 (1:66-2:10). However, according to the patent, while “[g]ravity flow filtration systems are well known in the art” (Appx407 (1:53)), “there is room for improvement in the filters used for gravity flow water filtration devices” (Appx409 (5:14-15)) “that exhibit both good water flow rates and high contaminant reduction.” Appx409 (5:20-21).

The patent describes the invention as improved gravity-fed water filters that achieve a Filter Rate and Performance (“FRAP”) factor<sup>2</sup> of about 350 or less according to a formula set forth in the patent. Appx409. For instance, claim 1 (from which all the other asserted claims depend) recites:

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<sup>2</sup> The term FRAP was “coined” in the ’141 patent. Appx204.

1. A gravity-fed water filter, comprising:

filter media including at least activated carbon and a lead scavenger, wherein the filter achieves a Filter Rate and Performance (FRAP) factor of about 350 or less according to the following formula:

$$FRAP = \frac{[V * f * c_e]}{[L * 2]}$$

where:

V = volume of the filter media (cm<sup>3</sup>),

f = average filtration unit time over lifetime L (min/liter),

c<sub>e</sub> = effluent lead concentration at end of lifetime L when source water having a pH of 8.5 contains 90-120 ppb (µg/liter) soluble lead and 30-60 ppb (µg/liter) colloidal lead greater than 0.1 µm in diameter, and

L = filter usage lifetime claimed by a manufacturer or seller of the filter (gallons).

Appx423 (34:6-27).

The embodiments disclosed as satisfying this FRAP factor are gravity-fed carbon-block water filters that utilize “multiple sub-blocks, each of the sub-blocks comprising filter media walls surrounding and defining a cavity receiving fluid.”

Appx409 (5:25-30). The patent describes one approach where “the filter media includes about 20-90 wt % activated carbon particles, and about 5-50 wt % binder material being interspersed with the activated carbon particles.” Appx409 (5:31-34). The patent further discloses that “a lead concentration in a final liter of effluent water filtered by the filter is less than about 10 µg/liter after about 151

liters[] (40 gallons) of source water filtration.” Appx409 (5:54-57). The specification emphasizes that “[t]he formulation of gravity-fed carbon blocks disclosed are *unique* in there [sic] ability to meet the required FRAP factor” and only provides examples of “gravity-flow carbon blocks that have a FRAP factor of less than 350.” Appx419 (26:63-67) (emphasis added).

While the patent mentions other filtration materials such as mixed media, nonwovens, hollow fibers, membranes, depth media, nanoparticles and nanofibers, and ligands (Appx419 (25:9-12, 26:30-37)), the patent does not disclose whether or how those materials achieve the claimed FRAP factor. In fact, carbon-block-based filtration systems are the only type of filtration systems disclosed and described in the patent as achieving the claimed FRAP factor. Appx409-410 (5:22-7:37). The only working examples disclosed in the patent as achieving the claimed FRAP are carbon-block filters. Appx420 (Table 1 (28:5-25)); Appx423 (Table 5 (33:15-55)). The patent also states that no other filter media that were tested or known to exist in the market could achieve the claimed FRAP factor. Appx419-420 (26:55-27:2). In particular, the specification states that “[n]o mixed media filters tested met the claimed FRAP factor range due to their inability to remove particulate lead.” Appx419 (26:61-63).

The specification further identifies specific problems with using filter media, other than the described carbon blocks, such as granular activated carbon with an

ion exchange resin. Appx408 (3:25-4:24). The specification explains that “[w]eak acid cation exchange resins can reduce the hardness of the water slightly, and some disadvantages are also associated with their use: first, they require a long contact time to work properly, which limits the flow rate.” Appx408 (3:57-60). The patent adds that “a further problem associated with blended media of granular carbon and ion exchange resin is that they have limited contaminant removal capability due to particle size and packing geometry of the granules.” Appx408 (3:64-67). The patent also discloses that “there are some drawbacks to using filter media with small granules” in that “[w]ater flow can be slow because the packing of the granules can be very dense, resulting in long filtration times” and that “small granules can be more difficult to retain within the filter cartridge housing.” Appx408 (4:20-24). The patent further teaches that “the carbon-based granular media that are used in the filters in question tend to be slightly hydrophobic,” so “while excellent water-media contact is needed for good flow distribution and good flow rates, the media actually tends to resist wetting by the water it is intended to filter.” Appx408 (4:61-67); *compare* Appx413 (14:39-41) (“[B]y maximizing the available surface area of the carbon, one can achieve a *carbon block* that is hydrophilic and readily absorbs water.”) (emphasis added).

During prosecution, the patentee emphasized the difficulty in designing a gravity-flow water filter that can achieve the required FRAP, and made clear that



there are “many variables and difficulty involved in designing a gravity-flow filter” and that “[t]he art of making an effective gravity flow, porous filter block, with excellent flowrates and excellent contaminant and lead removal under gravity flow is a very difficult task that is sensitive to shape and composition.” Appx35001-35003. The patentee added that “small differences in many variables can make large differences in molding, durability and performance.” Appx35004.

The intrinsic record thus evinces that the carbon-block chemistry and geometry are particularly important for achieving the claimed FRAP. Moreover, the intrinsic record provides no disclosure for achieving the claimed FRAP with other media filter compositions or structures.

## **II. THE COMMISSION PROCEEDINGS**

Relevant to this appeal, the Commission found no violation of section 337, finding the asserted claims invalid for lack of written description, lack of enablement, and indefiniteness. Appx3. Each of these issues, alone, is dispositive of the present appeal and supports affirming the Commission’s final determination of no violation of section 337.

### **A. Lack of Written Description**

The Commission found the asserted claims invalid for lack of written description. Appx27-28. Relying on the patent disclosure, expert testimony, and the inventors’ own admissions, the Commission found that one of ordinary skill in

the art at the time of the invention would not have understood that the inventors were in possession of certain types of media filter (other than carbon-block filters) that achieve a FRAP of 350 or less. Appx32-38. In particular, the Commission found that in view of the breadth of the claims and the unpredictability of the art with regard to achieving the claimed FRAP, contrasted with the lack of disclosure of working embodiments other than carbon blocks, the inventors were not, in fact, in possession of the invention relating to the other types of filter media, besides carbon block, as of the filing date. Appx33-37. The Commission correctly declined to adopt the ALJ's contrary findings, which (like Brita's arguments) focused on the wrong inquiry, *i.e.*, whether other filter media are well-known rather than whether they can predictably achieve the claimed FRAP. Appx35 (text & n.17).

The Commission observed that the “patent broadly claims any and all filtration media types with activated carbon and a lead scavenger that meet the functional FRAP factor limitation” and “identifies several filter media types that could be used with activated carbon and a lead scavenger, including mixed media, carbon blocks, nonwovens, hollow fibers, membranes, depth media, nanoparticles and nanofibers, and ligands.” Appx32-33 (citing Appx419 (25:9-12, 26:30-37)). The Commission found, however, that “the patent discloses only a single filtration media species—carbon block—that achieved the claimed FRAP factor of less than

350.” Appx33 (citing Appx378 (Abstract); Appx407 (1:15-18); Appx409 (5:24-33, 6:11-23); Appx410-411 (7:45-9:26); Appx23569-23571 (Freeman<sup>3</sup>-Tr. 1569:5-1571:12); Appx23428-23430 (Hatch<sup>4</sup>-Tr. 1428:2-1430:21)).

The Commission also found that “[f]or the other types of filter media, the patent provides no guidance or information about how or why these other types of media can achieve the requisite FRAP.” Appx33 (citing Appx419 (26:63-67); Appx23569-23571 (Freeman-Tr. 1569:5-1571:12); Appx23428-23430 (Hatch-Tr. 1428:2-1430:21)). The Commission concluded that “[t]he breadth of the claim contrasted with the lack of disclosure tends to indicate that the inventors were not, in fact, in possession of the invention relating to the other types of filter media, besides carbon block, as of the filing date.” Appx33.

The Commission also relied on the testimony of the inventors as confirming that the invention disclosed in the specification is supported only with respect to carbon-block filters and that “[the inventors] did not actually invent any non-carbon-block filters that would meet the FRAP factor limitation.” Appx36 (citing Appx22202-22204 (Knipmeyer<sup>5</sup>-Tr. 202:9-17, 203:5-204:12). In fact, the inventors admitted that they were only able to achieve the claimed FRAP when

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<sup>3</sup> Dr. Freeman was Brita’s expert before the Commission.

<sup>4</sup> Dr. Hatch was Respondents’ expert before the Commission.

<sup>5</sup> Dr. Knipmeyer is a named inventor of the ’141 patent.

they switched from granular media to carbon blocks. Appx36 (citing Appx32720 (Knipmeyer-Dep.Tr. 64:6-10); Appx32708 (Knipmeyer-Dep.Tr. 52:7-15; Appx32983-32986 (Knipmeyer-Dep.Tr. 327:15-330:5); Appx32227 (Reid<sup>6</sup>-Dep.Tr. 42:4-10); Appx32495-32497 (Saaski<sup>7</sup>-Dep.Tr. 114:17-116:2).

The Commission further rejected Brita's contention that the claims' recitation of "activated carbon" and a "lead scavenger" provides sufficient commonality among all filter media types such that they perform their function predictably and achieve a FRAP factor below 350.<sup>8</sup> Appx35 (n.17) ("[T]he evidence of record shows that the art is unpredictable with regard to achieving a FRAP factor below 350."); Appx53 (citing Appx23437 (Hatch-Tr. 1437:12-18 ("[T]his is a conundrum with the FRAP equation, which creates unpredictability in knowing what changing one variable is going to do to the others.")); Appx340 (n.88) (citing Appx22218-22219 (Knipmeyer-Tr. 218:20-219:11 ("[Y]ou can't change an individual characteristic [of FRAP]. They're all interrelated."))). The Commission found that "nothing in the patent disclosure would lead one of

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<sup>6</sup> Roger Reid is a named inventor of the '141 patent.

<sup>7</sup> Bruce Saaski is a named inventor of the '141 patent.

<sup>8</sup> Like Brita, the ALJ incorrectly focused on the predictability of the art with respect to gravity-fed water filters generally, rather than gravity-fed water filters *that can achieve a FRAP of less than 350*, as required by the asserted claims. Appx277-278.

ordinary skill in the art to understand how the claimed FRAP could be achieved with filter media other than carbon blocks based solely on the predictability of activated carbon and lead scavengers.” Appx35. Rather, the Commission concluded that “the express disclosures in the patent and the undisputed record evidence ... clearly and convincingly show that the invention provides adequate written description support only for what the inventors actually invented,” *i.e.*, “carbon-block filters that meet the FRAP factor limitation, and not for the full breadth of the claims that, as written, cover any filter media that can achieve the FRAP factor limitation.” Appx38.

#### **B. Lack of Enablement**

The Commission also determined that Respondents proved by clear and convincing evidence that the asserted claims are invalid for lack of enablement, declining to adopt the ALJ’s contrary findings. Appx38-39. The Commission relied on intrinsic and extrinsic evidence, including testimony from the inventors and technical experts, and found that each of the *Wands* factors supports a finding of lack of enablement. Appx48-58; *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The Commission concluded that, on balance, it would require undue experimentation “to make and use filters other than carbon blocks.” Appx48. Again, the Commission correctly focused its analysis on “making and using” the entire invention, *i.e.*, gravity-fed water filters *that achieve a FRAP of less than 350*,

and correctly rejected the ALJ's (and Brita's) arguments which focused instead on making and using gravity-fed water filters generally.

With respect to the first *Wands* factor (quantity of experimentation), the Commission found that “the patent disclosure itself provides no teaching on how any filter other than carbon blocks can achieve the required FRAP.” Appx48. The Commission noted that “[a]ll mixed media filters tested fail to adequately reduce total lead concentrations.” Appx48 (citing Appx422 (31:9-10, 31:54-55); Appx419 (26:63-67); Appx23569-23571 (Freeman-Tr. 1569:5-1571:12); Appx23428-23430 (Hatch-Tr. 1428:2-1430:21)). The Commission also found that “[d]espite these failures, the patent specification does not provide a road map for how mixed media materials, or any type of filter other than carbon blocks, can achieve the required FRAP.” Appx48-49. Rather, the Commission found, “[t]he only general quality common to every filter disclosed in the '141 Patent capable of achieving FRAP of less than 350 is carbon block, which is a completely different type of filter than any other type referenced in passing in the '141 Patent.” Appx49.

As to the second *Wands* factor (amount of guidance or direction presented), the Commission found that “[t]he only ‘guidance’ provided in the patent is the unremarkable listing of the names of several types of non-carbon-block filter media” and there is “no dispute that the patent does not teach how any of these media can achieve the claimed FRAP factor.” Appx50-51 (citing Appx419 (26:30-

37); Appx23569-23571 (Freeman-Tr. 1569:5-1571:12); Appx23428-23430 (Hatch-Tr. 1428:2-1430:21)). The Commission also noted Dr. Knipmeyer’s testimony that “non-carbon-block embodiments would involve creating ‘new technology’” and found that “the inventors indisputably had not attained any other filter material that achieved the claimed FRAP” and “all of their attempts were unsuccessful.”<sup>9</sup> Appx51 (quoting Appx32983-32984 (Knipmeyer-Dep.Tr. 327:15-328:6)). The Commission concluded that nothing in the patent would provide guidance to a person of ordinary skill in the art to make and use a non-carbon-block filter capable of achieving the claimed FRAP. Appx51.

As to the third *Wands* factor (working examples), there was no dispute that the patent only provides working examples of carbon-block filters as achieving the claimed FRAP, and thus this factor weighed in favor of lack of enablement. Appx51; Appx306.

Regarding the fourth *Wands* factor (nature of the invention), the Commission found that “despite the invention being directed broadly to gravity-fed water filters that can achieve FRAP of less than 350, carbon-block filters are the

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<sup>9</sup> As noted by the ALJ, “Brita took ten years and 7,326 hours of research and development to design a nonwoven filter that practices the ’141 patent.” Appx290 (n.77) (citing Appx23562-23563 (Freeman-Tr. 1562:18-1563:6)). In comparison, Brita asserts that it took only a few months between conception and reduction to practice to implement the claimed invention with carbon blocks. Appx194-195.

only filter media” described in the patent as achieving the claimed FRAP.

Appx52. The Commission explained that “the nature of the invention is not gravity-fed water filters *generally*, but gravity-fed water filters that achieve the claimed FRAP with any type of filter media,” and because the patent “discloses only carbon blocks to have achieved this FRAP, *Wands* factor 4 supports a finding of non-enablement.” Appx52 (emphasis added).<sup>10</sup>

Concerning the fifth *Wands* factor (state of the prior art), the Commission found no evidence of the “state of the prior art” to indicate that “a skilled artisan could have used other filter media to achieve the claimed invention without undue experimentation, especially when the evidence shows that the inventors themselves did not, and could not have done so without creating new technology.” Appx53.<sup>11</sup>

With respect to the sixth and seventh *Wands* factors (relative skill of those in the art and the predictability of the art), the Commission recognized that the

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<sup>10</sup> The ALJ credited Dr. Freeman’s testimony that “the nature of the invention is gravity-fed water filters,” and that “this is a well-known field and has been known for many decades if not longer.” Appx277 (citing Appx23519-23520 (Freeman-Tr. 1519:21-1520:6)); Appx306. But that testimony is irrelevant because the claimed invention is not directed to gravity-fed water filters generally but those that achieve a FRAP factor of 350 or less.

<sup>11</sup> The ALJ incorrectly found that the state of the prior art was “advanced” because “a skilled artisan could calculate the FRAP factor variables and the filter media types were known.” Appx308. Achieving the claimed FRAP of less than 350 with filter media types other than carbon block was not known. Appx52-53.



“individual variables, such as volume V, are well-known,” but that “the FRAP factor does not embody a well-known or predictable law of physics or natural correlation that could be applied by a person of ordinary skill in the art.” Appx53. The Commission relied on evidence showing that “the variables are interrelated such that changing one variable will change other variables in a nonlinear and unpredictable manner.” Appx53 (citing Appx23437 (Hatch-Tr. 1437:12-18)); *see also* Appx340 (n.88) (citing Appx22218-22219 (Knipmeyer-Tr. 218:20-219:11)).

As to the eighth *Wands* factor (breadth of the claims), the Commission found that the broad asserted claims are not enabled to their full scope and “[w]hile the patent specification discloses the names of various filter media embodiments, it indisputably fails to disclose how these filter media, other than carbon blocks, can achieve the claimed FRAP.” Appx56.<sup>12</sup>

On balance, and “[u]pon considering all of the *Wands* factors,” the Commission found that the asserted claims lack enablement. Appx56. The Commission concluded that “having only invented carbon-block filters to achieve the claimed FRAP, Brita attempts to claim sovereignty over the entire filter kingdom,” yet “it would take ‘painstaking,’ *i.e.*, undue, experimentation to find other types of filter materials that meet the claim requirements.” Appx57.

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<sup>12</sup> The ALJ recognized that the claims are “broad in that the filter media is not limited to carbon block.” Appx325.

### C. Indefiniteness

The Commission found that the scope of the claim term “filter usage lifetime claimed by a manufacturer or seller of the filter” cannot be ascertained with reasonable certainty and thus found the claims indefinite. Appx12; Appx16. The Commission rejected Brita’s attempt to rewrite the claim language to salvage the claims from indefiniteness.

The Commission vacated the ALJ’s construction (proposed by Brita) of the disputed term as “[t]he total number of gallons of water that a manufacturer or seller has validated can be filtered before the filter is replaced.” Appx12; Appx17. The Commission recognized “the difference between the filter usage lifetime being ‘claimed’ and the filter usage lifetime being ‘validated,’” reasoning that “a person of ordinary skill in the art would not exchange those terms as equivalent in meaning without specific guidance or reason to do so from the patent.” Appx17 (n.12) (citing dictionary definitions of “claim” (*e.g.*, “[c]ontend, maintain, assert”) and “validate” (*e.g.*, “to confirm or check the correctness of”)).<sup>13</sup> The Commission

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<sup>13</sup> The Commission observed that in an internal Brita memorandum, Dr. Knipmeyer proposed a definition that, on its face, would have expressed an objective validation requirement because it does not rely on the manufacturer’s or seller’s subjective claim: “filter usage lifetime is defined as the total number of gallons that can be filtered before the filter requires replacement.” Appx19 (n.14) (citing Appx22223-22224 (Knipmeyer-Tr. 223:24-224:25)). “The patentees, however, chose not to include this type of language in either the specification or the claims.” Appx19 (n.14).

thus found that “the patentees chose to use the phrase ‘claimed by,’ which is subjective language,” rather than the “objective word, ‘validate’ or a similar term, which would imply checking the claimed usage lifetime against a standard, benchmark, or other measure.” Appx18 (n.13) (referring to the dictionary definitions of the term “claim”); Appx17 (n.12).

The Commission also found that the patent specification fails to define how the claimed “filter usage lifetime” is determined. Appx18; Appx423 (34:25-26). Rather, the Commission observed that, consistent with the claim language, the specification defines “filter usage lifetime (L)” as “the total number of gallons that can be effectively filtered according to *claims presented* by the manufacturer or seller of the filter.” Appx18 (citing Appx419 (26:6-8)) (emphasis in original). The Commission also noted that “[t]ypically these *claims* are present on the product packaging in the form of instructions to a consumer as to a quantity of water that can be filtered before the filter should be changed” and “[t]he lifetime *claims* may also be presented in the manufacturer’s or seller’s advertising.” Appx18 (citing Appx419 (26:8-13)) (emphasis in original).

The Commission further noted that the specification discloses that “[t]ypically, filter usage lifetime claims require a substantiation process, and in some cases, a competitor may be able to challenge such claims in a judicial or non-judicial process.” Appx18-19 (citing Appx419 (26:14-15)) (emphasis added). The

Commission, however, found that “[t]his description of a substantiation process” is “permissive.” Appx18-19. Similarly, the Commission observed that the specification discloses that FRAP performance testing (which requires the measurement of the filter usage lifetime), “*may be* conducted according to the NSF/ANSI 53 protocol” and the specification incorporates the protocol by reference, but such “protocol is also permissive.” Appx19 (citing Appx419 (26:22-29)) (emphasis in original). The Commission thus concluded that “nothing in the specification requires substantiation or validation,” whether via the NSF/ANSI 53 protocol or otherwise. Appx19.

Even if the NSF/ANSI 53 protocol were required (it is not), the Commission observed that the patent does not require “a specific version” of that protocol. Appx25 (citing Appx419 (26:22-29)). The Commission was not persuaded by Brita’s assertion that the 2007 version of the NSF/ANSI 53 protocol must be the default methodology, when it had not even been established that the 2007 version of the methodology was used to test the filters disclosed in the patent. Appx23.

As further evidence that the patent does not mandate the 2007 NSF/ANSI 53 protocol, the Commission noted that testing under that protocol leaves a disclosed embodiment outside the scope of the claims. Appx23. The Commission explained that Table 5 of the patent discloses an embodiment, PT3-6, with a lifetime of 40 gallons. Appx23. Yet, this embodiment “could not have a lifetime of 40 gallons if

validation were required based upon NSF 53 (2007) lead reduction testing because the  $c_e$  of 13.3  $\mu\text{g/L}$  would exceed the 10.0  $\mu\text{g/L}$  imposed by the standard.” Appx24 (citing Table 5 (Appx423; Appx425)).

In addition to the variation in methodology of NSF/ANSI 53 and other protocols potentially encompassed by the patent, the Commission noted that the filter usage lifetime could depend on the contaminant being filtered and the quality of the water being filtered. Appx26; Appx32817-32819 (Knipmeyer-Tr. 161:25-163:1); Appx32933-32937 (Knipmeyer-Tr. 277:25-281:19). For instance, the Commission explained that the lifetime of the filter could be claimed based on impurities, other than lead, being filtered such as chlorine, arsenic, or chromium. Appx26 (citing Appx35005-35007 (Harrison<sup>14</sup>-Decl. ¶¶ 42-44)).

Against this intrinsic and extrinsic evidence, the Commission concluded that the disputed limitation, *i.e.*, lifetime “claimed by a manufacturer or seller” is not sufficiently cabined in a manner that can be understood by a skilled artisan with reasonable certainty, but rather, the scope of the claim subjectively changes based on how a manufacturer or seller claims a filter usage lifetime. Appx27. Accordingly, the Commission determined that the asserted claims of the patent are invalid for indefiniteness. Appx27.

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<sup>14</sup> Dr. Harrison was Respondents’ expert before the Commission.

## SUMMARY OF THE ARGUMENT

This Court should affirm the Commission’s finding of no violation of section 337 based on the Commission’s determination that the asserted patent claims are invalid for lack of written description, lack of enablement, and indefiniteness as there is no legal error in the Commission’s determinations and the Commission’s factual findings are supported by substantial evidence. If the Court affirms any of the Commission’s invalidity determinations, it need not reach the other invalidity issues raised on appeal. *See Solomon Techs., Inc. v. ITC*, 524 F.3d 1310, 1320 (Fed. Cir. 2008); *Sinorgchem Co., Shandong v. ITC*, 511 F.3d 1132, 1141 (Fed. Cir. 2007).

Brita effectively and improperly asks the Court to reweigh the evidence supporting the Commission’s factual findings. *See Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1365 (Fed. Cir. 2019). Brita does not even address the substantial evidence standard governing the Commission’s factual findings in its Argument section.<sup>15</sup> It is not enough for Brita to argue error in the Commission’s findings, but rather, Brita is required to show that the Commission’s determinations lacked substantial evidence.

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<sup>15</sup> Brita mentions the “substantial evidence” standard in its “Standard of Review” section but fails to apply it in the Argument section.

Brita also makes much of the ALJ's findings, but those findings are irrelevant on appeal. Indeed, this Court does not "review the correctness of the ALJ's initial decision or the correctness of the Commission's reversal" but the "final determination of the Commission." *See Spansion Inc. v. ITC*, 629 F.3d 1331, 1349 (Fed. Cir. 2010); *Deere & Co. v. ITC*, 605 F.3d 1350, 1358 (Fed. Cir. 2010) ("[The Commission] reviews all of the ALJ's findings *de novo*." (citing 5 U.S.C. § 557(b)); *Kay v. FCC*, 396 F.3d 1184, 1189 (D.C. Cir. 2005) (holding that an agency need not accept any of the ALJ's findings, "even if the ALJ's findings rested on his evaluation of the credibility of the witnesses").

More specifically, with respect to written description, Brita's arguments are premised on the incorrect assumption that the art is predictable. Substantial evidence, however, supports the Commission's factual findings that the art is not predictable with respect to the claimed FRAP. In view of the unpredictability of the art, the breadth of the claims, and the complete lack of disclosure of working embodiments with filter media other than carbon blocks, the Commission correctly determined that Respondents showed by clear and convincing evidence that the inventors did not have possession of the claimed subject matter as of the filing date, and therefore that the claims are invalid for lack of written description.

As to enablement, Brita merely establishes that filter media types other than carbon block are well-known, not that they can predictably achieve the claimed

FRAP. Substantial evidence supports the Commission’s findings that each of the *Wands* factors shows lack of enablement for the full scope of the asserted claims because the patent disclosure only enables carbon-block filters for achieving the claimed FRAP, not other filter media types.

As to indefiniteness, Brita essentially asks this Court to rewrite the claim term “filter usage lifetime claimed by a manufacturer or seller” to salvage the claims from indefiniteness. Both intrinsic and extrinsic evidence, however, support the Commission’s determination that the patentee failed to require an objective validation method to ascertain the scope of the disputed term and left it up to the subjective claim of the manufacturer or seller. Thus, a skilled artisan cannot ascertain the scope of the disputed term with reasonable certainty, thereby rendering the claims indefinite.

## **ARGUMENT**

### **I. STANDARD OF REVIEW**

Pursuant to the Administrative Procedure Act, this Court reviews the Commission’s legal conclusions *de novo*, and reviews the Commission’s factual findings for substantial evidence. *Bio-Rad Labs., Inc. v. ITC*, 998 F.3d 1320, 1327 (Fed. Cir. 2021) (citing 5 U.S.C. § 706). “A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding.” *Id.*



Patents are presumed valid, and invalidity must be established by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) (citing 35 U.S.C. § 282). Claim construction is a question of law, reviewed *de novo*, but may depend on subsidiary factual findings based on extrinsic evidence, reviewed for substantial evidence. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331-32 (2015). “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). “Indefiniteness, like claim construction, is a question of law that can involve underlying factfindings based on extrinsic evidence.” *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 97 F.4th 915, 936 (Fed. Cir. 2024).

To satisfy the written description requirement, the patent disclosure must “reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1016 (Fed. Cir. 2022) (citations omitted). “A determination that a patent is invalid for failure to meet the written description requirement” is “a question of fact,” reviewed for substantial evidence. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354-55 (Fed. Cir. 2010) (*en banc*).

As for enablement, the standard is whether a person skilled in the art can “make and use” the invention “without undue experimentation.” *In re Wands*, 858 F.2d at 736-37. Enablement is a question of law reviewed *de novo*, but it can be based on underlying facts, reviewed for substantial evidence. *See Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021).

## **II. SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION’S DETERMINATION THAT THE ASSERTED CLAIMS ARE INVALID FOR LACK OF WRITTEN DESCRIPTION**

“The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.” *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy’s Labs. Inc.*, 923 F.3d 1368, 1376-77 (Fed. Cir. 2019). The written description analysis “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art” and “[b]ased on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351. “[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Id.* For genus claims using functional language, “the specification must demonstrate that the applicant

has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.” *Id.* at 1349.

In finding that Respondents clearly and convincingly demonstrated that the patent lacks written description for filter media meeting the claimed FRAP factor other than carbon blocks, the Commission relied on the patent disclosure itself, expert testimony, and inventor testimony as to what they actually invented. In particular, substantial evidence supports the Commission’s determination that the inventors had no possession of filter media other than carbon blocks in view of the lack of disclosure of such filters in the patent itself, as contrasted with the breadth of the claims and the unpredictability of the art with respect to achieving a FRAP factor below 350. Where the art is unpredictable and the claims are broad, as is the case here, a higher “level of detail [is] required to satisfy the written description requirement.” *Id.* at 1351.

Brita failed to consider the entire claim language and focused on the wrong inquiry, *i.e.*, whether other filter media are well-known rather than whether they can predictably achieve the claimed FRAP.

**A. The Art Is Unpredictable with Respect to the Claimed FRAP**

As this Court held in *Ariad*, “the complexity and predictability of the relevant technology” is particularly relevant in determining whether the level of

detail provided in the patent specification is adequate to satisfy the written description requirement. *Ariad*, 598 F.3d at 1351.

The invention described and claimed in the patent is the ability to filter water to achieve a specific FRAP factor, not merely materials that are generically capable of purifying water. In other words, the filter media recited in claim 1 is defined by its ability to achieve a particular function. Notably, FRAP is not a term of art. It was coined in the patent to establish a performance metric. Yet, Brita in its brief ignores the elements of the actual claimed invention, and instead, focuses on the art of water filtration as a whole. But such an approach is not the law. As this Court's precedent makes clear, a patent "specification must describe an invention understandable to [a] skilled artisan and show that *the inventor actually invented the invention claimed.*" *Id.* (emphasis added).

The intrinsic and extrinsic records demonstrate that the relevant art of this invention, *i.e.*, filters that can achieve the required FRAP, is unpredictable. As the Commission found, nothing in the patent disclosure indicates how the variables of the claimed FRAP factor, which are characteristics of the filter media, interact to achieve the claimed FRAP performance of about 350 or less. Appx35 (text & n.17); Appx55. The Commission also rejected Brita's contention that the claims' recitation of "activated carbon" and a "lead scavenger" provides sufficient commonality among all filter media types such that they perform their function

predictably and achieve a FRAP factor below 350. Appx35 (text & n.17) (“[T]he evidence of record shows that the art is unpredictable with regard to achieving a FRAP factor below 350.”). Even the ALJ recognized that the art is unpredictable with respect to the FRAP factor:

[T]he FRAP Factor is not well-known, but is the novel feature of the invention. The individual components, such as volume V, are well-known, but as a whole, the FRAP factor does not embody a well-known law of physics because the variables are interrelated so that varying one variable leads to variations in others. ... For example, in practice, doubling one variable does not double the FRAP factor because other variables also change depending on the interrelationship of the water filter, activated carbon and lead scavenger.

Appx340 (n.88) (citing Appx23437 (Hatch-Tr. 1437:12-18); Appx22219 (Knipmeyer-Tr. 219:7-11)).

While the intrinsic record supports the claimed FRAP factor with carbon-block filters, it is silent as to how to predictably achieve the claimed FRAP with different compositions and structures. The intrinsic record makes clear that the carbon-block chemistry and geometry are important because they maximize surface area and contaminant removal. *See e.g.*, Appx413 (14:39-41) (“[B]y maximizing the available surface area of the carbon, one can achieve a carbon block that is hydrophilic and readily absorbs water.”); Appx416 (19:16-18) (“The multi-core shape serves to increase surface area and volume of material that is active for filtration and contaminant removal.”); *compare* Appx408 (3:64-67) (“A

further problem associated with blended media of granular carbon and ion exchange resin is that they have limited contaminant removal capability due to particle size and packing geometry of the granules.”); Appx408 (4:61-64) (“[A]chieving adequate flowrate is also problematic because the carbon-based granular media that are used in the filters in question tend to be slightly hydrophobic.”).

Similarly, during prosecution of the patent, the patentee emphasized the difficulty in designing a gravity-flow water filter that can achieve the required FRAP, and made clear that there are “many variables and difficulty involved in designing a gravity-flow filter” and that “[t]he art of making an effective gravity-flow, porous filter block, with excellent flowrates and excellent contaminant and lead removal under gravity flow, is a very difficult task that is very sensitive to shape and composition.” Appx35001-35003. The patentee added that “small differences in many variables can make large differences in molding, durability and performance.” Appx35004.

Consistent with that intrinsic record, the Commission correctly credited Dr. Hatch’s testimony that the state of the art of gravity-fed water filters is unpredictable with respect to the claimed FRAP equation:

So when you change one of these factors, you do not know what is going to be the final result of your FRAP value, and ... this is a conundrum with the FRAP equation, which

creates unpredictability in knowing what changing one variable is going to do to the others and end up in a result.

Appx23437 (Hatch-Tr. 1437:12-18); Appx53; Appx35 (text & n.17). Dr. Hatch further testified that even though the inputs to the FRAP equation are interrelated, the patent disclosure fails to explain the impact of changing one factor on the others. Appx23437-23438 (Hatch-Tr. 1437:19-1438:8); Appx23416 (Hatch-Tr. 1416:12-19) (“[W]hen you look at the formula, the variables there are interrelated, and, as a matter of fact, if you begin changing one of those variables to achieve a different FRAP number, the other variables will most likely change, and end up with an unpredictable result.”).

The Commission also correctly credited the testimony of Dr. Knipmeyer, a named inventor, who testified that a skilled artisan could not change an individual input to the FRAP equation and expect a corresponding FRAP factor change because all the inputs are “interrelated.” Appx54 (Appx22218-22219 (Knipmeyer-Tr. 218:20-219:3)).<sup>16</sup> In particular, Dr. Knipmeyer explained that the performance of a filter must be considered “holistically” because the FRAP variables are not truly mathematical variables, but “characteristics of the filter.” Appx22218-22219; Appx54. In fact, the inventors were only able to achieve the claimed FRAP when

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<sup>16</sup> To the extent Brita suggests that each of the FRAP variables is independently “controllable,” Brita-Br. 7, Brita is wrong in view of the interrelatedness of those variables.

they switched from granular media to carbon block, and thus, their testimony confirms that the claimed FRAP cannot be predictably obtained with filter media other than carbon block. Appx36 (citing Appx32720 (Knipmeyer-Dep.Tr. 64:6-10 (“Q. And – and as part of inventing this patented technology, did you invent any activated carbon and ion exchange resin filter that would have met this FRAP limitation? A. Not at that time, no.”)); Appx32708 (Knipmeyer-Dep.Tr. 52:7-15 (“Q. What – what’s the delta? What’s the magic formula? ... A. – we changed technology from a granular media to a carbon block. Q. Did the current granular media solutions at the time, were they able to solve this problem? A. Not that I’m aware of.”))).

Brita is wrong that the invention described and claimed in the patent is directed to a “predictable art.” Brita-Br. 30, 33. Of course, activated carbon and lead scavengers will perform as predicted when applied to water to remove lead and other impurities, but that is not the dispositive point. The relevant question is the filter media’s ability to filter water effectively *to achieve the claimed FRAP factor*—which is in no way predictable. As discussed above, that art is unpredictable beyond the disclosed carbon-block embodiment with respect to the claimed FRAP.

Brita also argues that the ALJ found Dr. Hatch’s testimony not “credible” while Dr. Freeman’s testimony was “unrebutted.” Brita-Br. 13, 40 (citing



Appx23513-23514 (Freeman-Tr. 1513:24-1514:2) (“The activated carbon and lead scavengers don’t know or care what filter format they’re in. They perform their function independent of how they’re organized and what their geometry is.”)). Like the ALJ, however, Brita failed to consider the entirety of the claim language and incorrectly focused on the known elements of the claims. Dr. Freeman’s testimony was similarly flawed and inconsistent with the intrinsic record, which evinced the particular importance of the chemistry and geometry of carbon-block filters. Thus, on review, the Commission correctly declined to credit Dr. Freeman’s flawed testimony. Appx35.

#### **B. The Specification Fails to Support the Full Breadth of the Claims**

The ’141 patent broadly claims any and all filtration media types with activated carbon and a lead scavenger that meet the functional FRAP factor limitation. Appx423 (34:5-8). As the Commission found, the claim is broadly directed to a filter that has activated carbon and a lead scavenger, and it can cover any type of filter media which includes those two compounds. Appx32. Yet, the patent discloses only a single filtration media species—carbon-block—that has been demonstrated to achieve the claimed FRAP. *See, e.g.*, Appx378 (Abstract); Appx407 (1:15-18); Appx409 (5:24-33, 6:11-23); Appx410-411 (7:45-9:26). While the intrinsic record supports achieving a FRAP of 350 or less with carbon-block filters, it is silent on how to achieve the claimed FRAP with different

compositions and structures. In view of the unpredictability of the art and the breadth of the claims, the patent specification fails to provide the level of detail required to satisfy the written description requirement. *Ariad*, 598 F.3d at 1351.

Indeed, the patent mentions several filter media that can be used with activated carbon and a lead scavenger, but it only exemplifies the carbon-block filters as capable of achieving the required FRAP. Appx419 (25:9-12, 26:30-37). The specification identifies specific problems with using filter media, other than the described carbon blocks, such as granular activated carbon with an ion exchange resin (*i.e.*, lead scavenger). Appx408 (3:25-4:24). The specification explains that “[w]eak acid cation exchange resins can reduce the hardness of the water slightly, and some disadvantages are also associated with their use: first, they require a long contact time to work properly, which limits the flow rate.” Appx408 (3:51-62). The patent adds that “[a] further problem associated with blended media of granular carbon and ion exchange resin is that they have limited contaminant removal capability due to particle size and packing geometry of the granules.” Appx408 (3:64-67). Yet, the specification provides no guidance on how to overcome these problems to achieve the claimed FRAP with filter media other than carbon block. Appx33.

As the Commission found, Dr. Hatch testified that one of ordinary skill in the art reading the patent would not understand that the inventors were in

possession of filter media, other than carbon blocks, that achieve a FRAP of 350 or less, in view of the absence of working examples with non-carbon-block media and the unpredictability of the art with respect to the claimed FRAP. Appx33; Appx23427-23430 (Hatch-Tr. 1427:21-1430:1).<sup>17</sup> Dr. Hatch explained that a person of skill in the art reading the patent would conclude that “the inventors did not possess” filter materials other than carbon blocks achieving the claimed FRAP:

[T]here are no mixed-media filters tested that met the claimed FRAP factor range due to their inability to remove particulate lead, ... and none of them performed according to the claims, and, again, the rest of those membranes, nonwoven, depth media, nanoparticles, nanofibers and ligands, there are no working examples presented in the '141 patent.

Appx23444-23445 (Hatch-Tr. 1444:10-1445:3).

Dr. Freeman, Brita's expert, confirmed that there is no disclosure in the patent of working examples with non-carbon-block media filters and none of them achieves the required FRAP. Appx23569-23570 (Freeman-Tr. 1569:5-1570:13); Appx33. Brita argues that “the non-carbon-block filters the inventors tested were all prior-art filters.” Brita-Br. 26. Whether they are prior art filters or not, there is simply no disclosure in the intrinsic record and no evidence of non-carbon-block

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<sup>17</sup> Brita failed to address the Commission's reliance on Dr. Hatch's testimony, and incorrectly states that “inventor testimony” was the Commission's “only extrinsic evidence.” Brita-Br. 42; Appx33; Appx35 (text & n.17); Appx53-55.

filters achieving a FRAP of 350 or less as of the filing date. Nor is there any guidance for achieving the claimed FRAP with non-carbon-block filters.

In fact, the inventors admitted that they did not invent non-carbon-block filters that achieve the claimed FRAP. Appx36; Appx22202-22204 (Knipmeyer-Tr. 202:9-17 (invention utilized only carbon block), 203:5-9 (did not invent membrane filter), 203:10-14 (did not invent nonwoven filter), 203:15-19 (did not invent depth media filters), 203:20-24 (did not invent nanoparticle filter), 203:25-204:2 (did not invent nanofiber filter), 204:3-8 (did not invent granular media filter), 204:9-12 (did not invent or disclose granular activated carbon and ion exchange resin combination meeting FRAP limitation), 204:13-17 (no disclosure in the patent of any filters other than carbon block)). The evidence of record thus supports the Commission's finding that the specification fails to provide adequate written description support to the asserted claims.

*ScriptPro LLC v. Innovation Associates, Inc.*, 833 F.3d 1336 (Fed. Cir. 2016), does not save Brita's case. Brita argues that the written description requirement here is satisfied because the original claims contained the same limitations. Brita-Br. 34. But the original patent disclosure also fails to disclose how to achieve the required FRAP with filter media other than carbon blocks, and Brita does not contend otherwise. Thus, the original disclosure is similarly inadequate. *See Ariad*, 598 F.3d at 1350 (“[G]eneric claim language appearing in

*ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed.”); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (“While it is true that an originally filed claim can provide the requisite written description to satisfy section 112, ... nothing in [the original claim] or the specification constitutes an adequate and enabling description of all seamless [discrete wavelet transforms].”).<sup>18</sup> *ScriptPro* is also inapposite because it was undisputed that the inventors had possession of the claimed subject matter as of the filing date. *ScriptPro* examined the adequacy of the written description where the specification focused on an embodiment that disclosed sorting and storing based on patient-identifying information, while the claims were not so limited. *ScriptPro*, 833 F.3d at 1341. Because the (broader) original claims were part of the specification, the Court reversed the district court’s finding that “the specification limited the invention to storing prescription containers based on patient name.” *Id.* at 1342.

The facts here are more akin to *ICU Medical*, where this Court found that because “the specification describes only medical valves with spikes,” “a person of

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<sup>18</sup> Brita faults the Commission for relying on pharmaceutical cases, but those cases are not limited to their facts and the principles stated therein are broadly applicable to different arts. Brita-Br. 43 (citing Appx37-38). Nor does the present case involve “an admittedly well-known genus in the predictable mechanical arts,” as Brita contends. *Id.* The invention involves both chemical and mechanical aspects. Appx31-32 (citing Appx22174-22175 (Knipmeyer-Tr. 174:4-13, 175:8-24)).

skill in the art would not understand the inventor ... to have invented a spikeless medical valve.” *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1378 (Fed. Cir. 2009). Similarly, because the specification here describes only carbon-block filters as achieving a FRAP of 350 or less, and the art is unpredictable with respect to the claimed FRAP, one of ordinary skill would not understand the inventors to have invented non-carbon-block filters that meet the required FRAP.

Lastly, Brita correctly notes that the written description requirement “does not demand either examples or an actual reduction to practice.” Brita-Br. 36-37 (citing *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006)). Brita, however, fails to mention that in *Falko-Gunter*, “there was undisputed testimony that ... publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with the locations of the ‘essential regions’” and that “[t]he person of ordinary skill in the art would clearly have possessed such knowledge.” *Falko-Gunter*, 448 F.3d at 1365. As the Court explained, “a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement.” *Id.* at 1368. In contrast, here, the disclosure of non-carbon-block filters was at best cursory, and achieving the claimed FRAP factor was neither known nor predictable. *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1342 (Fed. Cir. 2021) (finding written description not satisfied because the patent failed to disclose

representative species or common structural features of the claimed genus to identify which species would function as claimed).

**C. The Disclosed Carbon-Block Filter Embodiments Are “Unique” and Are Not Representative of All Media Filters**

The Commission correctly rejected Brita’s contention that the claims’ recitation of “activated carbon” and a “lead scavenger” provides sufficient commonality among all filter media types such that they perform their function predictably and achieve a FRAP factor below 350. Appx35. As discussed above, only carbon-block filters were shown to be capable of achieving the required FRAP of less than 350. Appx33. Carbon-block filters, however, are a different type of filter than the other filter media mentioned in the patent.

As described in the patent, carbon-block filters are made from powdered activated carbon that is bonded with a binder and then formed into “an integrated, porous, composite, carbon block.” Appx413 (13:22–24). Carbon-block filters are distinct from other media filters such as mixed-media filters that use granular activated carbon with an ion exchange resin. Appx408 (3:25-4:24). As discussed above, the intrinsic record emphasizes the importance of the chemistry and geometry of carbon-block filters while describing the issues encountered with other media filters, *e.g.*, granular media filters. *See supra* Parts II.A, II.B. The specification explained that the carbon-block filters are “*unique*” in their ability to meet the required FRAP. Appx419 (26:63-67). Additionally, as discussed *supra*,

the inventors confirmed that they were only able to achieve the claimed FRAP with carbon-block filters but no other media filters.

Against this factual backdrop, substantial evidence supports the Commission’s finding that the claims’ recitation of “activated carbon” and a “lead scavenger” does not provide sufficient commonality among all filter media types such that they perform their function predictably and achieve a FRAP factor below 350. Appx35. For instance, Table 5 of the specification shows a FRAP above 350 with, for example, granular mixed-media filters containing granular carbon (*i.e.*, activated carbon) and ion exchange resin (*i.e.*, lead scavenger). Appx423 (Table 5). In view of the unpredictability of the art with respect to the claimed FRAP and the breadth of the claims, Brita’s contention that a single species (carbon block) is representative of the entire genus of media filters is without merit. Brita-Br. 38-39. Brita’s flawed premise, that this case involves “predictable factors,” negates any argument that “‘a single embodiment’ can be representative” of the entire genus. *Id.* In contrast, this Court’s decision in *Ajinomoto*, on which Brita improperly relies, affirmed the Commission’s determination that the patent provided adequate written description support because the specification disclosed “a representative number of species” and “structural features common to the genus,” and “the genus ... was already well explored in the relevant art.” *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019).



At bottom, Brita is attempting to monopolize more than it invented—carbon blocks. This Court should reject Brita’s improper bid and affirm the Commission’s determination of lack of written description. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (“[T]he purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.”) (quotation omitted).

### **III. SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION’S DETERMINATION THAT THE ASSERTED CLAIMS LACK ENABLEMENT**

The Supreme Court has made clear that a patent’s specification must enable the full scope of the invention as defined by the claims and “[t]he more one claims, the more one must enable.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023).

While “it is not required that every embodiment covered by the claims be exemplified,” “it may suffice to give an example (or a few examples) *if* the specification also discloses ‘some general quality ... running through’ the class that gives it a ‘peculiar fitness for the particular purpose.’” *Id.* at 611 (quoting *The Incandescent Lamp Patent*, 159 U.S. 465, 475 (1895)) (emphasis added). In essence, “[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed.

Cir. 2010) (quotations omitted). This Court has long used the *Wands* factors in determining whether a disclosure requires undue experimentation. *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1367 (Fed. Cir. 2023).

Here, substantial evidence supports the Commission’s determination that Respondents established lack of enablement by clear and convincing evidence. In particular, the patent fails to teach a person of ordinary skill in the art how to make and use media filters, other than carbon blocks, that can achieve a FRAP of 350 or less. Brita, again, incorrectly focuses on the predictability of the art with respect to gravity-fed water filters generally, but fails to address the substantial evidence supporting the Commission’s determination that the art is unpredictable with respect to the claimed FRAP.

**A. Under the *Wands* Factors, the Full Scope of the Asserted Claims Lacks Enablement.**

The Commission properly analyzed enablement under the *Wands* factors, and found that each of the factors supports lack of enablement. Appx48-58; *supra* Statement of the Case, Part II.B. In particular, both the intrinsic and extrinsic evidence support the Commission’s determination that the art is neither advanced nor predictable with respect to the claimed FRAP factor. Nor is there any guidance in the specification for making and using non-carbon-block filters achieving a FRAP of 350 or less. Brita makes much of the ALJ’s findings. But this Court has explained that it reviews the “final determination of the Commission” itself, and

does not “review the correctness of the ALJ’s initial decision or the correctness of the Commission’s reversal [of the ALJ].” *Spansion*, 629 F.3d at 1349.<sup>19</sup> In any event, like Brita, the ALJ also improperly focused on “gravity-fed water filters generally,” rather than “gravity-fed water filters that achieve the claimed FRAP.” Appx52. While it may be predictable to make filters with certain compositions or physical properties, substantial evidence supports the Commission’s determination that a person of ordinary skill in the art cannot predictably make and use filters, other than carbon-block filters, that *achieve a FRAP of 350 or less*.

### Wands Factors 1-3

In particular, as relevant to *Wands* factor 1 (quantity of experimentation), factor 2 (the guidance provided in the specification), and factor 3 (disclosure of working examples), the specification makes clear that formulations of gravity-fed carbon blocks invented are “unique” in their ability to meet the required FRAP and

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<sup>19</sup> Brita also relies on *Morall v. DEA*, 412 F.3d 165 (D.C. Cir 2005), to argue Commission error in disregarding the ALJ’s findings. *Morall*, however, is inapposite. In *Morall*, the D.C. Circuit vacated the DEA’s revocation of a physician’s registration because DEA had consistently “declin[ed] to revoke the registration of any other physician in a comparable context, or even under significantly more troubling circumstances” and because DEA offered “no explanation” for the departure from its consistent policy and provided no “reason for rejecting the ALJ’s decision to credit Dr. Morall’s account.” *Id.* at 178-81. Here, the Commission has not departed from any of its practice or precedent and the Commission in its opinion provided a detailed reasoning for not adopting the ALJ’s findings. Appx38-58.

that no other type of filter material tested achieved the required FRAP. Appx419-420 (26:55–27:2); Appx48-51. Indeed, as noted in detail *supra* in the Statement of the Case, Part I, the specification identifies several specific problems with using filter media other than carbon blocks to achieve adequate filter performance. For instance, the patent states that “the carbon-based granular media that are used in the filters in question tend to be slightly hydrophobic,” so “while excellent water-media contact is needed for good flow distribution and good flow rates, the media actually tends to resist wetting by the water it is intended to filter.” Appx408 (4:61-67); Appx408 (3:64-67) (“A further problem associated with blended media of granular carbon and ion exchange resin is that they have limited contaminant removal capability due to particle size and packing geometry of the granules.”). Comparatively, the patent discloses that carbon blocks “maximiz[e] the available surface area of the carbon, [such that] one can achieve a carbon block that is hydrophilic and readily absorbs water,” Appx413 (14:39-41), and “[t]he multi-core shape increases surface area and the volume of material active for filtration and contaminant removal.” Appx416 (19:16-18).

Most relevant, the specification discloses that all of the mixed-media filters (besides carbon block) failed to remove lead effectively (Appx422 (31:54–55)), and all of them resulted in filtration rates “above the preferred FRAP range (0-350).” Appx423 (33:23–24); Appx423 (33:60–63, Table 5) (carbon blocks “all

had FRAP factors below 350, while the mixed media and cylindrical filters had FRAP factors above 350”). Thus, the Commission correctly found that “[d]espite the[] failures [of mixed-media filters], the patent specification does not provide a road map for how mixed media materials, or any type of filter other than carbon blocks, can achieve the required FRAP,” Appx48-49, and “[t]here is nothing in this disclosure that would guide a skilled artisan to develop a non-carbon-block filter that achieves the required FRAP.” Appx50.

Brita argues that the exemplified non-carbon-block filters are prior art filters. Brita-Br. 26-27. But there is no disclosure of any working examples of achieving FRAP with non-carbon-block filters, whether they are prior art or otherwise, as Brita’s own expert and the named inventors admitted. Appx23569 (Freeman-Tr. 1569:5-20); Appx22202-22204 (Knipmeyer-Tr. 202:9-17, 203:5-204:17).

Moreover, during prosecution of the patent, the applicants emphasized the difficulty in designing a gravity flow water filter that can achieve the required FRAP. Appx35001-35004. Yet, neither the patent disclosure nor its expansive prosecution history provide a solution or “general quality” to overcome the shortcomings of non-carbon-block filters. *Amgen*, 598 U.S. at 611 (quoting *Incandescent Lamp*, 159 U.S. at 465). In fact, the inventors admit that they achieved the claimed FRAP precisely when they switched from granular media to carbon blocks. Appx32708 (Knipmeyer-Dep.Tr. 52:7-15) (the “magic formula”

was to change technology from a granular media to a carbon block, and granular media options could not solve the problem). Thus, the intrinsic record demonstrates that the carbon-block chemistry and geometry are uniquely important for achieving a FRAP of 350 or less, and the specification lacks any guidance for predictably making non-carbon-block filters that can achieve the claimed FRAP.

Consistent with the intrinsic record, the Commission correctly credited Dr. Hatch's testimony that the patent provides no guidance or direction for modifying the working examples to implement the asserted claims in a mixed-media (*i.e.*, non-carbon-block) filter. Appx23427-23428 (Hatch-Tr. 1427:21–1428:10); Appx48-49. Rather, as the Commission found, “[t]he only ‘guidance’ provided in the patent is the unremarkable listing of the names of several types of non-carbon-block filter media” and “[t]here is ... no dispute that the patent does not teach how any of these media can achieve the claimed FRAP factor.” Appx50-51 (citing Appx419 (26:30-37); Appx23569-23571 (Freeman-Tr. 1569:5-1571:12); Appx23428-23430 (Hatch-Tr. 1428:2-1430:21) (testifying that the specification provides no “examples or directions” for achieving the claimed functional FRAP performance with filter media other than carbon block)).

Wands Factors 4-8

The lack of disclosure and the unpredictability of the art are particularly problematic given the breadth of the claims (*Wands* factor 8).<sup>20</sup> Here, the Commission correctly determined that *Wands* factor 4 (nature of the invention), factor 5 (state of the prior art), factor 6 (relative skill in the art), and factor 7 (predictability of the art) weigh against enablement. Appx52-56. In particular, the Commission correctly noted that “the nature of the invention is not gravity-fed water filters generally, but gravity-fed water filters that achieve the claimed FRAP with any type of filter media.” Appx52. As such, the Commission disagreed that the state of the art was “advanced” or “predictable.” Appx52-55.

Rather, the Commission explained that achieving the claimed FRAP is unpredictable because the FRAP variables are interrelated such that changing one variable will change the other variables in a nonlinear and unpredictable manner. Appx53-55. As discussed *supra* Part II.A, Dr. Hatch testified that there is “a

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<sup>20</sup> Brita does not dispute that the asserted claims are broad and cover all media filters capable of achieving a FRAP of 350 or less. Brita, however, suggests that like *McRo*, this case involves “an abstract assertion of breadth, without concrete identification of matter that is not enabled but is or may be within the claim scope.” *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1101 (Fed. Cir. 2020); Brita-Br. 41. Not so. In this case, the Commission found lack of enablement based on Respondents’ concrete identification of non-carbon-block filters which are encompassed by the claims but not enabled by the specification with respect to achieving a FRAP of 350 or less.

conundrum with the FRAP equation, which creates unpredictability in knowing what changing one variable is going to do to the others [or the final result].”

Appx23437 (Hatch-Tr. 1437:12-18); Appx53. While Dr. Hatch acknowledged that a person of ordinary skill in the art can determine the  $V$ ,  $f$ ,  $c_e$ , and  $L$  variables (if properly defined) and calculate the resulting FRAP factor, he explained that those variables are “interrelated” such that the art is “unpredictable” with respect to achieving a FRAP of 350 or less. Appx53 (citing Appx23434-23435 (Hatch-Tr. 1434:18-1435:20); Appx23437-23438 (Hatch-Tr. 1437:19-1438:8) (testifying that even though the inputs to the FRAP equation are interrelated, the patent disclosure fails to explain the impact of changing one factor on the others).

Even the ALJ recognized the interrelatedness of the FRAP variables, finding that “in practice, doubling one variable does not double the FRAP factor because other variables also change depending on the interrelationship of the water filter, activated carbon and lead scavenger.” Appx340 (n.88) (citing Appx22219 (Knipmeyer-Tr. 219:7-11)). In particular, Dr. Knipmeyer’s testimony confirmed that a skilled artisan could not change an individual variable of the FRAP equation and predict the effect on the FRAP factor because all the variables are interrelated. Appx53-54 (citing Appx22218-22219 (Knipmeyer-Tr. 218:20-219:11)). Dr. Freeman’s (Brita’s expert) contrary testimony that skilled artisans “could use those same starting materials and apply them to a different geometry” to get “comparable



performance,” Appx23521 (Freeman-Tr. 1521:19-24), cited in Brita-Br. 23, is contradicted by the intrinsic evidence which demonstrate the particular importance of the carbon-block chemistry and geometry in achieving the claimed FRAP, as discussed above.

*Balancing of the Wands Factors*

After finding that each of *Wands* factors weighs against enablement, the Commission correctly concluded that, on balance, the asserted claims are not enabled. Appx56. The Commission found that “having only invented carbon-block filters to achieve the claimed FRAP, Brita attempts to claim sovereignty over the entire filter kingdom,” yet “it would take ‘painstaking,’ *i.e.*, undue, experimentation to find other types of filter materials that meet the claim requirements.” Appx57.

In support of enablement, Brita essentially argues that media filters other than carbon blocks are well-known, but that focuses on the wrong inquiry and does not negate the Commission’s lack of enablement determination. Brita is also wrong that the Commission did not disturb the ALJ’s credibility determinations (Brita-Br. 22), but rather, the Commission correctly credited Dr. Hatch’s testimony (over Dr. Freeman’s) because it properly focused on the claimed FRAP and was consistent with the intrinsic record. Appx48-57. Thus, substantial evidence supports the Commission’s finding that a person of ordinary skill in the art cannot

make and use the full scope of the invention without undue experimentation, particularly in view of the breadth of the claims, the lack of working examples and guidance with respect to non-carbon-block filters, and the unpredictability of the art for achieving the claimed FRAP.

**B. Contrary to Brita’s Assertion, this Court’s Precedent Supports the Commission’s Lack of Enablement Determination**

In addition to failing the enablement test under each of the *Wands* factors, this Court’s precedent demonstrates that the Commission correctly found lack of enablement under the present facts. As this Court has emphasized, while the specification need not “describe how to make and use every possible variant of the claimed invention,” there must be sufficient guidance to enable the full scope of the claims without undue experimentation, particularly where the claims recite “broad functional language.” *Amgen*, 987 F.3d at 1085, 1087-88 (quotation omitted). Just as in *Amgen*, the asserted claims here recite “broad functional language,” namely, a FRAP of 350 or less, but the specification fails to provide sufficient guidance for achieving the claimed FRAP with filter media other than carbon blocks. *See id.*

The structural limitations recited in the claims, including the activated carbon and lead scavenger are also insufficient to provide guidance to achieve the claimed invention. This is evidenced by Table 5 of the specification which shows a FRAP above 350 with other materials, including, granular mixed-media filters.

Appx423 (Table 5); *see also* *ALZA*, 603 F.3d at 940 (finding lack of enablement where the specification only described osmotic dosage forms and did not provide sufficient guidance for person of ordinary skill in art to make non-osmotic dosage forms); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008) (finding lack of enablement where the claims broadly recite video games and movies, but the specification does not teach how the substitution and integration of a user image would be accomplished in movies); *Liebel–Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007) (finding lack of enablement because “nowhere does the specification describe an injector with a disposable syringe without a pressure jacket” even though the full scope of the invention includes injectors with and without a pressure jacket). Thus, the patent disclosure fails to identify a quality common to every functional embodiment, and “leave[s] a scientist ... forced to engage in ‘painstaking experimentation’ to see what works.” *See Amgen*, 598 U.S. at 614 (quoting *Incandescent Lamp*, 159 U.S. at 475).

Brita’s reliance on *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 707 F.3d 1330 (Fed. Cir. 2013) and *Alcon Research Ltd., v. Barr Laboratories*, 745 F.3d 1180 (Fed. Cir. 2014), is misplaced. Brita-Br. 29-31. *Cephalon* simply holds that extensive experimentation does not necessarily rise to the level of undue experimentation where “the experiments involve repetition of known or commonly used techniques.” *Cephalon*, 707 F.3d at 1338-39. That is not the case here where

the claims require a FRAP of 350 or less but the specification fails to provide any guidance on how to predictably make and use non-carbon-block filters achieving the claimed FRAP. Nor does the specification identify a general quality or commonality (other than trial and error) that would allow a person of ordinary skill in the art to achieve the claimed FRAP with non-carbon-block filters. *See Amgen*, 598 U.S. at 611.

Similarly, *Alcon* is inapposite. In *Alcon*, the Court found that the “claimed methods comprise only a single step” and the experts agreed it was “routine.” *Alcon*, 745 F.3d at 1189. Moreover, while the claims required “some increase in chemical stability,” they did not require “a particular level of stability or a particular magnitude of increase” and provided “step by step” guidance on how to practice the claim. *Id.* In contrast, here, the patent provides no guidance on how to achieve the claimed FRAP with filter media other than carbon blocks.

**IV. THE COMMISSION CORRECTLY DETERMINED THAT THE TERM “FILTER USAGE LIFETIME CLAIMED BY A MANUFACTURER OR SELLER OF THE FILTER” CANNOT BE ASCERTAINED WITH REASONABLE CERTAINTY, THEREBY RENDERING THE CLAIMS INDEFINITE**

A patent claim is indefinite if a person of ordinary skill in the art reading the claim in light of the specification and prosecution history is unable to ascertain the scope of the invention with “reasonable certainty.” *Nautilus*, 572 U.S. at 910-11. “In construing claims, the analytical focus must begin and remain centered on the

language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point [ ] out and distinctly claim [ ] the subject matter which the patentee regards as his invention.’” *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

In finding the claims indefinite, the Commission relied on intrinsic and extrinsic evidence, including dictionary definitions, expert declaration, and inventor testimony. In view of the record, the Commission correctly declined to rewrite the claim language to salvage the claims from indefiniteness.

**A. The Claims Demonstrate a Subjective “Lifetime” Limitation, and There Is No Support for Rewriting the Claim Language to Include an Objective “Validation” Term**

The Commission correctly vacated the ALJ’s construction (proposed by Brita) of the term “L[-]filter usage lifetime claimed by a manufacturer or seller of the filter (gallons)” as meaning “[t]he total number of gallons of water that a manufacturer or seller has validated can be filtered before the filter is replaced.” Appx12; Appx17. As the Commission found, the patentees specifically chose the subjective phrase “claimed by” in the disputed limitation rather than an objective word, “validate” or a similar term (*e.g.*, verified), which would imply checking the claimed usage lifetime against a standard, benchmark, or other measure. Appx18 (n.13). The dictionary definitions of “claim” and “validate” are distinct and support the Commission’s finding that “a person of ordinary skill in the art would

not exchange those terms as equivalent in meaning without specific guidance or reason to do so from the patent.” Appx17 (n.12) (citing dictionary definitions of “claim” (*e.g.*, “[c]ontend, maintain, assert”) and “validate” (*e.g.*, “to confirm or check the correctness of”)).<sup>21</sup>

Consistent with the claim language, the patent specification provides an express definition for “filter usage lifetime (L)” as “the total number of gallons that can be effectively filtered according to *claims* presented by the manufacturer or seller of the filter.” Appx419 (26:5-7) (*emphasis added*).

Despite admitting that the “lifetime” limitation “means the usage lifetime a manufacturer or seller ‘elects to present’ such as ‘on product packaging’ or in other ‘advertising,’” Brita-Br. 44, Brita fails to recognize that a manufacturer’s “election” to present such claim is, ultimately, subjective. Appx18-19; *see also Datamize, LLC v. Plumtree Software, Inc.*, 417 F. 3d 1342, 1350 (Fed. Cir. 2005) (holding that a claim limitation fails to provide sufficient notice of its scope if it depends “on the unpredictable vagaries of any one person’s opinion” and is “purely subjective”). Indeed, Brita argues without support that the disputed limitation refers to the “number of gallons of water for which the filter can be used

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<sup>21</sup> Brita cites *BASF* in its Standard of Review section, but fails to recognize that the Commission’s factual findings that are based on extrinsic evidence are entitled to deference. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (“[A]ny factual findings about extrinsic evidence relevant to the question [of indefiniteness] ... are reviewed for clear error.”).

before replacement.” Brita-Br. 44-45. Brita entirely erases the requirement that the “filter usage lifetime” be “claimed by a manufacturer or seller of the filter” and essentially asks this Court to redraft the claims to sustain their validity. The Court should decline Brita’s invitation to do so. *Chef Am., Inc. v. Lamb Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (“[C]ourts may not redraft claims, whether to make them operable or to sustain their validity.”).

Brita also strays from the claim language and attempts to rely on “surrounding words” to argue that “an ordinarily skilled artisan would understand that the recited ‘filter usage lifetime’ is based on the filter’s ability to reduce lead, verified through testing of the effluent lead concentration by the manufacturer or seller.” Brita-Br. 45. In so arguing, Brita wrongly conflates two distinct claim limitations: (1) “ $c_e$ ,” which is directed to “[the] effluent lead concentration at end of lifetime L,” and (2) “L,” which simply recites “filter usage lifetime claimed by a manufacturer or seller of the filter (gallons).” Appx423 (34:7-26). Brita cannot merge these two limitations to save its claims; indeed, each claim limitation must be given meaning. *See CAE Screenplates Inc. v. Heinrich Fiedler GmbH*, 224 F.3d 1308, 1317 (Fed. Cir. 2000). Moreover, the  $c_e$  limitation which relates to “the effluent lead concentration *at end of lifetime L*,” does not further define or limit the lifetime L limitation and provides no support for Brita’s attempt to rewrite that claim term. Appx423 (34:7-26) (emphasis added).

Nor does the specification's definition of the "lifetime" term which includes the phrase "effectively filtered," require that the manufacturer's claim be "based on verification using objective measurements," as Brita contends. Brita-Br. 46. Indeed, the phrase "effectively filtered" does not negate that the "[performance] claims [are] *presented by* the manufacturer or seller of the filter," without constraint on whether or how the manufacturer or seller elects to support such claims. Appx419 (26:5-7) (emphasis added). To illustrate the subjective nature of the term, manufacturers may in fact present a lifetime claim that is not even related to the amount of lead that the filter can reduce, but rather is related to the "lowest common denominator" contaminant that the filter can remove. Appx26 (citing Appx35005-35007 (Harrison-Decl. ¶¶ 42-44)). Accordingly, the lifetime of a filter could be claimed based on other impurities being filtered such as chlorine, arsenic, or chromium. Appx26. In other words, if a filter can effectively remove lead for up to 60 gallons but only up to 40 gallons for chlorine, the lifetime claimed by the manufacturer can be just "40 gallons," which demonstrates the subjective nature of a manufacturer's claim and the consequential effect of the manufacturer's claiming decision. Appx26. Thus, Brita's argument that the Commission failed to rely on evidence showing any "consequential" or "material variation" is without merit. Brita-Br. 15, 54. Given the potential variability in the disputed limitation, potential competitors cannot determine with reasonable certainty whether or not they



infringe the asserted claims. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993) (“[C]laims ... [must be] sufficiently precise to permit a potential competitor to determine whether or not he is infringing.”).

**B. The Patent Fails to Provide an Objective Methodology that Would Circumscribe the Disputed Limitation**

In view of the plain claim language and the express definition in the specification, it is entirely up to the subjective prerogative of “a manufacturer or seller” whether and how to support its “claim[]” with respect to a “filter usage lifetime.” Appx423 (claim 1). While the patent discloses potential validation methodologies to determine filter usage lifetime, the patent uses permissive language, which is insufficient to depart from the plain language of the claims. *See i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 844 (Fed. Cir. 2010) (finding that “permissive language” does not limit the disputed claim term).

Indeed, nothing in the intrinsic evidence requires objective substantiation or validation, only permissive options, which supports indefiniteness. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (“Where, as here, we are faced with a ‘purely subjective’ claim phrase, we must look to the written description for guidance,” and finding the claim indefinite because “sufficient guidance is lacking in the written description of the asserted patents.”). As the Commission determined, the specification does not mandate how manufacturers are to determine and claim the lifetime limitation. Appx18;

Appx423 (34:25-26). The specification merely discloses permissive options that “[t]ypically these *claims* are present on the product packaging in the form of instructions to a consumer as to a quantity of water that can be filtered before the filter should be changed” and “[t]he lifetime claims may also be presented in the manufacturer’s or seller’s advertising.” Appx18; Appx419 (26:8-13).

Further emphasizing the permissive and subjective nature of the lifetime limitation, the specification provides that “[t]ypically,” *i.e.*, not always, “filter usage lifetime claims require a substantiation process.” Appx18-19 (citing Appx419 (26:14-15)) (emphasis added). Additionally, the protocol disclosed for such substantiation is also permissive. In particular, the specification provides that FRAP performance testing (which includes the measurement of the filter usage lifetime), “*may be* conducted according to the NSF/ANSI 53 protocol.” Appx19 (citing Appx419 (26:22-29)); Appx419 (25:53-54) (“*Preferably*, the source water is prepared as defined in the NSF/ANSI 53 protocol (2007).”) (emphasis added). As further evidence that the specification does not mandate testing under the 2007 NSF/ANSI 53 protocol, the Commission found (and Brita does not dispute) that the PT3-6 embodiment would be outside the scope of the claims. Appx23. The Commission explained that PT3-6 “could not have a lifetime of 40 gallons if validation were required based upon NSF 53 (2007) lead reduction testing because

the  $c_e$  of 13.3  $\mu\text{g/L}$  would exceed the 10.0  $\mu\text{g/L}$  imposed by the standard.” Appx23 (citing Table 5 (Appx423; Appx425)).

Brita admits that the claims are not limited to the NSF/ANSI 53 standard but argues that the standard merely provides a default method for manufacturers to validate filter usage. Brita-Br. 53. Brita thus confirms that manufacturers are free to elect a different validation methodology to support their filter usage lifetime claim, thereby rendering the claims indefinite. *See Teva Pharm. USA, Inc. v. Sandoz Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015) (finding the term “molecular weight” indefinite where the term could mean peak average molecular weight (Mp), number average molecular weight (Mn), or weight average molecular weight (Mw), and “[t]he claims do not indicate which measure to use”); Appx20 (citing, *inter alia*, *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 634-35 (Fed. Cir. 2015) (“[T]he existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite.”)).

Brita suggests that even if a different validation methodology were to “double the FRAP factor” that would still be acceptable. Brita-Br. 54 (discussing PT3-6 embodiment). Brita’s attorney argument is unsupported and insufficient to inform a skilled artisan about the scope of the claim with reasonable certainty. Nor does Brita’s argument comport with the law and the facts in this case. The law

requires ascertaining the scope of the “lifetime” term with reasonable certainty. It does not merely require that the FRAP factor remain under 350. Furthermore, there is no evidence that a different methodology would merely double the FRAP factor. Appx53 (“[I]n practice, doubling one variable does not double the FRAP factor because other variables also change depending on the interrelationship of the water filter, activated carbon and lead scavenger.”) (citing Appx22219 (Knipmeyer-Tr. 219:7-11)).

Brita further argues that some states require certification under industry standards, Brita-Br. 48, but that argument similarly fails.<sup>22</sup> As discussed above, the specification makes clear that the scope of the term “filter usage lifetime” is not circumscribed by any particular industry standard. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (“[Extrinsic evidence] may not be used to vary or contradict the claim language. Nor may it contradict the import of other parts of the specification.”) (citation omitted). Nor can the scope of a claim term be dependent on advertising guidelines or state regulations. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1385 (Fed. Cir. 2014)

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<sup>22</sup> Brita failed to raise this argument before the Commission, and it is therefore waived. *See* 19 C.F.R. § 210.43(b)-(c) (providing that any argument not raised in a petition to the Commission or response thereto “will be deemed to have been abandoned and may be disregarded by the Commission”); *see also Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362-63 (Fed. Cir. 1999) (finding an issue waived for failure to raise it before the Commission).

(“We have long recognized that, although the understanding of a claim term can evolve over time, the literal scope of a patent claim cannot have different meanings at different times.”) (quotations omitted).

**C. This Court’s Precedent Supports the Commission’s Indefiniteness Determination**

The Commission’s indefiniteness determination is consistent with this Court’s precedent and Brita’s attempt to distinguish the precedent is without merit. In particular, like *Datamize* and *Interval Licensing*, the claimed “filter usage lifetime claimed by a manufacturer or seller” is subjective and entirely dependent on a manufacturer’s choice of whether and how to present its lifetime claim. Indeed, both cases involved claim terms, “unobtrusive manner” in *Interval Licensing*, and “aesthetically pleasing” in *Datamize*, that this Court found indefinite because they were highly subjective, lacking in objective boundaries, and lacking sufficient guidance to ascertain the scope of claims. *Interval Licensing*, 766 F.3d at 1371 (finding the claim term “unobtrusive manner” indefinite because it is highly subjective, lacks objective boundaries, and sufficient guidance as to its scope “is lacking in the written description”) (citing *Datamize*, 417 F.3d at 1352 (finding the claim term “aesthetically pleasing” indefinite because, even though the preferred embodiment provided “examples of aesthetic features,” the specification did not indicate “what selection of these features would be ‘aesthetically pleasing’”)).

Brita also relies on *Wellman, Inc. v. Eastman Chemical Co.*, 642 F.3d 1355, 1368-69 (Fed. Cir. 2011) to argue that “[i]ndustry practice, especially when detailed in the intrinsic record itself, is ... highly relevant to understanding claims’ meaning.” Brita-Br. 51. In *Wellman*, however, the claims recited “a heating crystallization exotherm peak temperature ... *as measured by differential scanning calorimetry*” (“DSC”) and the Court found that “well known industry standards” may be used to ascertain “specific moisture conditions for DSC testing.” *Wellman*, 642 F.3d at 1358, 1367. In contrast, here, the claims do not require any testing methodology for ascertaining the “lifetime” limitation and merely recite a “lifetime claimed by a manufacturer or seller of the filter.” Appx423 (34:25).

Brita’s reliance on *Biosig* is similarly misplaced. Brita-Br. 50-51 (citing *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374 (Fed. Cir. 2015)). In *Biosig*, this Court found that the intrinsic evidence showed that a skilled artisan would understand the scope of the invention with reasonable certainty because “spaced relationship” means “neither infinitesimally small nor greater than the width of a user’s hands.” 783 F.3d at 1382. That is, unlike here, the intrinsic evidence defined the scope of the claim limitation and did not vary that scope depending on testing methodology.

Lastly, the Commission did not shift the burden to Brita to prove its claims were not indefinite. Brita-Br. 55 (citing Appx16-27). Rather, in exercising its

claim construction duty, the Commission declined to rewrite the claim language as proposed by Brita, and agreed with Respondents that “claimed” is subjective and distinct from “validated.” Appx16-27; Appx6817-6824. Short of improperly reading a specific validation requirement into the claims, there can be no dispute that clear and convincing evidence supports indefiniteness.

### CONCLUSION

For the foregoing reasons, the Commission respectfully requests that the Court affirm the Commission’s final determination of no violation of section 337.

Respectfully submitted,

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Date: June 24, 2024

## CERTIFICATE OF SERVICE

I, Panyin A. Hughes, hereby certify that, on June 24, 2024, I caused a copy of the foregoing **RESPONSE BRIEF OF APPELLEE INTERNATIONAL TRADE COMMISSION**, to be served on counsel of record via the Court's CM/ECF system.

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## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(b)(3), I hereby certify that the attached brief complies with the type-volume limitation and typeface requirements Federal Rule of Appellate Procedure 32(a)(7) and Federal Circuit Rules 32(b)(1) and 32(b)(2). The brief has been prepared in a proportionally spaced typeface using Microsoft Office 365, in Times New Roman 14-point font. The brief contains a total of 13,969 words including 13,979 words obtained from the word-count function of the word-processing system, including all footnotes, annotations, and claim language, and a manual count of 10 words appearing in the graphics and figures.

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